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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,444

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Anthony Pantages

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,444	Applicant(s) PANTAGES ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10 and 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/12/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 09/18/2009.

The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 10/12/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5, 7-10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., hereinafter **Green** (U.S. Patent No. **5,674,231**) in view of Fontaine et al., or **Fontaine** (U.S. Patent No. **6,447,540**).

Claims 1, 3, 5, 7-8, 17, 19, 20, and 22: Green discloses a method for delivering a closure element in a blood vessel **104**, the closure element being carried by a carrier assembly **42** slidable on an outer surface of an elongate member **30**, the elongate member comprising and at least partially overlying the carrier assembly, the elongate member being provided with a locator member **60** slidably associated therewith, the

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locator member having one or more expandable positioning elements **62**, **64** on its distal portion, the method comprising inserting the distal end of the elongate member into an opening through tissue, advancing the locator member distally from the distal end of the elongate member, expanding the one or more positioning elements, withdrawing the locator member until the positioning elements contact tissue, advancing the carrier assembly towards the distal end of the elongate member, and deploying a closure element **22** from the carrier assembly within the opening to substantially seal the opening (Figures 1-4, 7, 10-11 and col. 5, lines 45-67, col. 6, lines 1-8, col. 7, lines 18-67, col. 8, lines 1-52).

Green discloses the claimed invention, including advancing the carrier assembly towards the distal end, except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member, the skin comprising a weakened region extending towards the distal end of the elongate member and expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced, and the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Fontaine teaches a skin or sleeve **16** with a weakened region overlying at least a portion of an outer surface between a carrier assembly **20** and a distal end of an elongate member **12** and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member and expand as it advances or moves

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longitudinally (see abstract and Figure 7). Fontaine also teaches a slippery surface on the sleeve (col. 7, lines 29-38). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Green with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

Claim 2: Green discloses removing the elongate member from the opening (col. 8, lines 44-52).

Claim 9: Green discloses the opening through tissue communicating with a blood vessel, and wherein the deploying step comprises substantially sealing the opening from blood flow therethrough with the closure element. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 10: Green discloses coupling the carrier assembly to a proximal end of the elongate member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 14: Green discloses contracting said positioning elements and withdrawing said locator member. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 15: Green discloses the distal end of the elongate member being inserted into the lumen of a blood vessel and wherein the positioning elements of the locator member are expanded within the lumen of a blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claim 16: Green discloses the step of withdrawing the locator member causes the

positioning elements to come into contact with the wall of the blood vessel. See explanation for Claims 1, 17, 19, 20, and 22 above.

Claims 18 and 21: Green and Fontaine disclose the claimed invention except for the blood vessel being the femoral artery. It would have been obvious to one of ordinary skill to provide the blood vessel as being a femoral artery in Green and Fontaine, since it was known in the art that the femoral artery is a blood vessel and that the vascular hole closure device and method may be applied to any blood vessel as desired.

3. Claims 12-13 rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. **5,674,231**) in view of **Fontaine** (U.S. Patent No. **6,447,540**), as applied to claim 1 above, and further in view of **Martinez** (U.S. Patent No. **5,593,412**).

Claims 12-13: Green and Fontaine disclose the claimed invention except for the skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands.

Martinez teaches a skin comprising a plurality of longitudinal slots, the slots opening as the carrier assembly is advanced, thereby expanding the skin, and the slots being staggered relative to one another such that the skin assumes a zigzag mesh configuration as it expands (Figures 1-5 and col. 4, lines 53-67 and col. 5, lines 1-2). It would have been obvious to one of ordinary skill in the art to provide a skin having a plurality of slots assuming a zigzag mesh configuration, as taught by Martinez, to Green and Fontaine since it was known in the art that such a configuration allows for more

flexibility and lateral, axial, and longitudinal expansion.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Green** (U.S. Patent No. **5,674,231**) in view of (U.S. Patent No. **6,447,540**), as applied to claim 1 above, and further in view of Kanner et al., hereinafter **Kanner** (U.S. Patent No. **5,868,755**).

Claim 6: Green and Fontaine disclose the claimed invention, including the carrier assembly advancing towards the distal end except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface.

Kanner teaches a skin **1** being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface (col. 4, lines 1-16). It would have been obvious to one of ordinary skill in the art to provide a skin bonded to the outer surface to the elongate member, as taught by Kanner, to Green and Fontaine, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

Response to Arguments

5. Applicant's arguments filed 09/18/2009 have been fully considered but they are not persuasive.

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6. Applicant argues that Green does not teach the surgical clip **22** being carried by the pusher tube **42** or the clip support **34** being slidable with respect to the support shaft **30**. The examiner disagrees. As set forth in the rejection, the surgical clip **22** is carried or advanced by carrier assembly or “pusher tube **42** [“arcuate engagement fingers 44a and 44b project distally from the pusher tube 42 to engage the crescent spaced aperture 83 defined in the ball portion 26 of clip 22” (col. 6, lines 14), thus the clip is carried by tube 42] , which is “mounted coaxial with support shaft **30** and is configured to translate with respect thereto in response to manipulation of actuation handle **18** to drive surgical clip **22**” (Figures 4-5) col. 5, line 62 to col. 6, line 8). The fact that element 34 is not slidable on shaft 30 is irrelevant since in the rejection element 42 is equated with the carrier assembly that is slidable on the elongate member as recited in the claims.

7. Applicant also generally argues that Fontaine does not teach that advancing a carrier assembly causes the splittable sleeve member (“skin”) to be disrupted from the proximal end of the sleeve member toward the distal end of the sleeve member, since the splitting mechanisms appear to be inflating a balloon or manually splitting the sleeve. However, the teaching of Fontaine demonstrates that splitting a sleeve **18** can be achieved by an assembly disposed within the sleeve which expands the sleeve’s diameter, causing it to split. Further evidence is taught by Fontaine who teaches that another splitting mechanism is a “bulbous end on the catheter” or the device covered by the sleeve, such that “[l]ongitudinal movement of the bulbous catheter end with respect to the sleeve splits at least the portion of the sleeve extending over the [catheter]” (col. 4, lines 47-54; Figures 15A-15B). If one were to modify Green by placing a splittable

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sleeve over the elongate member and the carrier assembly, the proximal to distal advancement of the carrier assembly **42** would distally advance the clip **22** (which would be likened to the “bulbous end” of Fontaine) which may spilt the sleeve from its proximal end to its distal end, due to expansion of a weakened region in the sleeve. As maintained above, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Green with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734